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JOHN P. PARISE
HOFFMAN-LA ROCHE, INC
3340 KINGSLAND STREET
NUTLEY, NJ 07110

In re Application of
Alfred Binggeli et al
Serial No.: 08/711,339
Filed: September 6, 1996
Attorney Docket No.: 4019/135

PETITION DECISION

This is in response to applicants' petition under 37 CFR 1.144, filed November 11, 1998 (Certificate of Mailing date), requesting withdrawal of an improper restriction requirement.

FILE HISTORY

A review of the file history shows that this application was filed under 35 U.S.C. 111 on September 6, 1996. The application, as filed, contains claims 1-136, all directed to compounds, claim 1 being the only independent claim. The examiner in a first Office action, mailed October 16, 1997, setting a one month shortened statutory period for response, required an election of a single disclosed species prior to examination on the merits, further indicating that a generic concept would be developed from the elected species and examined. Applicants responded by adding claim 137 (replacing claim 41 to correct a spelling error) to a single disclosed species and electing the species of claim 137. No traversal of the requirement was made. The examiner in the first Office action on the merits, mailed March 23, 1998, setting a three month shortened statutory period for response, examined the elected species and determined the generic concept by setting forth the definitions for the individual variables of the generic structure in claim 1. The examiner then identified the claims which included the examined generic concept as well as additional non-elected concepts as claims 1-17, 20, 32-33, 35-39, 42-45, 47, 68-72, 74, 77 and 87-90 as well as claim 137. Claims which did not contain the generic concept were identified as claims 18-19, 21-31, 34, 46, 48-67, 73, 75-76, 79-86 and 91-136 and were withdrawn from consideration. Claims 40, 78 and 137 were indicated as allowable if placed in independent form or made dependent from an allowable claim. Claims 1-17, 20, 32-3, 35-39, 42-45, 47, 68-72, 74, 77 and 87-90 were objected to as containing non-elected subject matter, but would be allowable if restricted to the examined generic concept. Applicants responded on July 16, 1998 (including a one month extension of time) vigorously traversing the restriction requirement as to the election of species and the generic concept determined by the examiner arguing that the provisions of M.P.E.P. 803.02 had not been followed. The examiner in a Final Office action, mailed September 25, 1998, setting a three month shortened statutory period for response, maintained the requirement rebutting applicants' arguments by asserting that the compounds encompassed by the generic structure of claim 1 were so diverse as to be patentably distinct and thus properly restricted. This petition followed on November 11, 1998.

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DISCUSSION

M.P.E.P. 803.02 gives guidance as to Office practice in applications containing Markush type claims, which claim 1 appears to be.

If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.

Since the decisions in *In re Weber*, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.

This subsection deals with Markush - type generic claims which include a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language. A Markush - type claim can include independent and distinct inventions. This is true where two or more of the members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. 103 with respect to the other member(s). In applications containing claims of that nature, the examiner may require a provisional election of a single species prior to examination on the merits. The provisional election will be given effect in the event that the Markush - type claim should be found not allowable. Following election, the Markush - type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. If Markush - type claim is not allowable over the prior art, examination will be limited to the Markush - type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration.

As an example, in the case of an application with a Markush - type claim drawn to the compound C - R, wherein R is a radical selected from the group consisting of A, B, C, D, and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD, or CE. The Markush - type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush - type claim and claims to the elected species shall be rejected, and claims to the non - elected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the rejected claims would be made final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush - type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush - type claim with respect to a non - elected species, the Markush - type claim shall be rejected and claims to the non - elected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all non - elected species. Should applicant, in response to this rejection of the Markush - type claim, overcome the rejection, as by amending the Markush - type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush - type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush - type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush - type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

A review of claim 1, the only independent claim in the application shows a structure which contains eight primary variables. Of these variables, at least Q, for example, significantly affects

the structural context of the claimed compounds since its presence creates a bridged six-membered ring compound which is significantly different from a simple six-membered ring compound when Q is absent. A bridged ring compound is so significantly different from a non-bridged compound that they are recognized in the art as separate inventions. Of the other variables, R¹ has two options (aryl or heterocycle), R³ has five options, X has eight options, W has three options and Z has nine options. However R² has 5,000,000 options and R⁴ has over 5000 options. When all permutations are calculated, more than 11 quadrillion different compounds are encompassed within claim 1. (This does not include variations due merely to difference in an alkyl carbon chain or the multitude of variations encompassed within the term "heterocycle"(R¹) which is not further defined in the claim 1.) The 540 page specification sets forth over 150 examples of how specific compounds are made, each example containing multiple specifically identified compounds.

As set forth in M.P.E.P. 803.02, unity of invention, as defined by the courts, exists where (1) the claimed compounds share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility (emphasis added). In this application, all of the compounds claimed are described as renin inhibitors thus satisfying requirement (1) of a common utility. However, the specification fails to indicate what substantial structural feature is essential to that utility. In view of this it is considered that the examiner has acted properly in initially requiring an election of a single disclosed species for examination purposes. In setting forth the requirement the examiner failed to properly advise applicants to set forth a listing of all claims readable on the elected species stating instead that the examiner would determine the genus or generic concept based on the elected species. This oversight, however, does not appear to have significantly affected the prosecution of the application. Subsequent to applicants' election of the species of claim 137, the elected species was examined and the examination then expanded to related species, which in the opinion of the examiner would be unpatentable over the elected species, to a reasonable number from which a generic concept was determined by the examiner. The genus was examined based on common utility and substantial common structural feature(s) determined to be essential to that utility and found to be allowable. Such is consistent with Office policy and practice and is not contrary to M.P.E.P. 803.02 or 809.02. Restriction between patentably independent and distinct inventions (compounds) even when set forth in the same claim has always been an option which the Office may exercise in examining an application.

Applicants argue that the Office is required to perform a search on the elected species and all claims readable thereon, including claim 1. This the examiner has done to the extent of the elected species and the generic concept developed therefrom with respect to all claims which read thereon, determining which fell within the scope of the elected genus and which did not. Applicants, on the other hand, would have the examiner examine the full breadth of claim 1 since it contains the elected species. To do so would in effect nullify the election of species of the restriction requirement. Applicants argue that the Office is not authorized to derive or determine the generic concept to be examined based on the species elected. Applicants are correct in this area. However, applicants did not offer any suggestions as to a proper genus or argue that the genus determined by the examiner was improper except with respect to the entire scope of claim 1. Applicants were properly afforded an opportunity to elect a single disclosed species in response to the requirement and had ample opportunity in making the election to suggest to the examiner a generic concept narrower than the broad concept of claim 1, but encompassing the

elected species. This applicants did not do. The genus determined by the examiner is reasonable and not in conflict with the rules or guidelines set forth. Applicants further argue that withdrawal of claims, or parts of claims, from examination is, in fact, a rejection of those claims. Such is not the case. The examiner has identified parts of the claims which are broader than or outside of the elected species and generic concept derived therefrom and required the claims to be limited to the elected concept. This comports to a determination by the examiner to the discovery in the claims of inventions which are patentably separate and distinct from the examined invention and which could support separate patents and a requirement that the application's claims be limited to a single invention as required by statute. It does not preclude applicants' filing of additional applications to the separate and distinct inventions.

Applicants cite *In re Weber* for the concept:

If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the sub-genera would be defined by the examiner rather than the applicant, it is not inconceivable that a number of the fragments would not be described by the specification.

Such argument is specious in this particular application since it would be beyond an examiner's and the Office's skill, resources, time and expertise to consider a claim to over 11 quadrillion (11,000,000,000,000,000) compounds.

DECISION

Applicants' petition to withdraw the restriction requirement as improper is **DENIED** for the reasons stated above..

Any request for reconsideration of this decision or a renewed petition must be filed within **TWO MONTHS** of the mailing date of this decision in order to be considered timely. Extensions of time may be available under 37 CFR 1.136(a).

Should there be any questions with respect to this decision, please contact William R. Dixon, Jr., by mail addressed to: Director, Technology Center 1600/2900, Washington, D.C. 20231, or by telephone at (703)308-3824 or by facsimile transmission at (703) 308-7922.



John Kittle
Director, Technology Center 1600/2900